REMARKS

I. STATUS OF CLAIMS

Claims 1-12, 15-24, 26-33, 35-57, 59-66 and 68-72 are pending in the application, and rejected. Claims 13, 14, 25, 34, 40, 58 and 67 have previously been cancelled. Claims 1, 20, 28, 29, 30, 31, 33, 42, 43, 62 and 68 are currently amended. Support for the claim amendments can be found in the specification as originally filed. No new matter has been added.

II. REJECTIONS UNDER 35 U.S.C. § 103(a)

Claims 1-12, 15-24, 43-57, 59-66 and 68-72 are rejected under 35 U.S.C. §103(a) as being unpatentable over Kaplan (U.S. Pat. No. 5,342,348) in view of Mariant (U.S. Pat. No. 6,187,027) and further in view of Phelps (U.S. Pat. No. 5,382,259).

The Examiner has given no indication that he has considered the Applicants' response filed on December 12, 2007. Applicant respectfully requests that the Examiner take note of the Applicants' argument and answer the substance of it as required by MPEP §707.07(f).

> Where the applicant traverses any rejection, the examiner should, if he or she repeats the rejection, take note of the applicant's argument and answer the substance of it.

MPEP §707.07(f)

MPEP §707(f) also provides that the Examiner must address all arguments which have not already been responded to in the statement of the rejection. Applicants find no such explanation as to the non-persuasiveness of the arguments made in the December 12, 2007 response, which are now repeated herein.

Reiterating the same rejection as in his July 25, 2007 office action, the Examiner states that Kaplan discloses in Figures 1-6C a device for treating and enlarging body lumens that anticipates a device for occluding a body lumen passageway comprising a tubular member 4, having a first end and a second end (fig. 1A), one end is open (1B), a lumen extending therein 12, to the open end, which is expandable in the body lumen from a first configuration with a first transverse dimension to a second larger configuration with a second larger dimension (col. 3, lines 11-16), the tubular member includes an open framework structure (the openings in the tubular member provide an open framework), a fibrous member (14, 16), made of polymeric

material (col. 11, lines 18-21), fibrous member is woven strands (col. 7, lines 30-33), of biocompatible material (col. 11, lines 18-20), connected to the tubular member (Fig. 1B), the fibrous material is disposed within the lumen (fig. 1B), in a plurality of section (fig. 1A), at a first end (fig. 1A), the tubular member is made of stainless steel (col. 5, lines 10-14), the tubular member includes anchoring members (col. 5, lines 48-50), to secure the tubular member to the walls of a body lumen, the tubular member expands from a first configuration to a second larger configuration by the release of radially compressive force, the tubular member is formed of a superelastic material (col. 3, lines 11-15), the second configuration of the tubular member has a radially expandable diameter which increase along at least a section thereof from the first end of the tubular member to the second end of the tubular member (col. 3, lines 11-16) the tubular member as a lattice framework (2A), the lattice framework is thin-walled metallic tube having a pattern of cuts 10, along the tubular member, the framework includes a braid of wire (a helical strand woven into the tubular member, col. 3, lines 23-26) helical coil (col. 5, lines 55-58), the tubular member is configured to promote epithelialization (col. 7, lines 53-66), tissue growth (col. 7, lines 52-66), capable of provoking an inflammatory response (col. 8, lines 55-58), through copper (which is old and well known in the art), the inflammatory material is radioactive (col. 5, lines 18-21) and the tubule member has an open wall structure (fig. 1A). The Examiner states that Kaplan does not disclose that the fibrous material is bundled strands but that Mariant teaches in figures 1-6 an occlusion device comprising fibers 12 that are in bundles (col. 5, lines 12-116) and the fibers permit tissue growth (col. 5, lines 45-51). The Examiner states that it would have been obvious to one having ordinary skill in the art at the time the invention was made to substitute the fiber taught by Mariant for the fibers disclosed by Kaplan in order to permit tissue growth into the tubular member.

The Examiner then states that Phelps teaches in figures1-6C a fibrous member that is a mesh 130. The fibrous mesh as taught by Phelps could be used to increase tissue growth around and inside the tubular open framework. The Examiner rejected claims 26-27 under 35 U.S.C. §103(a) as being unpatentable over the references as applied to the claims above and further in view of Phelps. The Examiner states that Phelps teaches in figures 1-5 an occluding device comprising a plug attached to fibers (col. 3, lines 15-20). The plug, states the Examiner, is capable of provoking an inflammatory response. The Examiner states it would have been obvious to one having ordinary skill in the art at the time that the invention was made that the

plug as taught by Phelps could be used to provide an inflammatory response to stimulate tissue growth, while at the same time occluding the fallopian tube.

The Examiner rejected claims 28-33 and 35-42 under 35 U.S.C. 103(a) as being unpatentable over Kaplan in view of Mariant and further in view of Phelps stating that Kaplan discloses in figures 1-6C a device for treating body lumens, that anticipates a contraceptive, substantially as claimed, as set forth above. According to the Examiner, Mariant teaches in figures 1-6 an occluding device comprising fibers to promote tissue growth. Phelps, states the Examiner, teaches in figures 1-5 fibers formed as a mesh. The Examiner states that it would have been obvious to one of ordinary skill in the art that the fibers as taught by Mariant could be formed as a mesh as taught by Phelps [and presumably substituted for the filaments of Kaplan] in order to allow tissue growth in the lumen and around the tubular member.

The Examiner states that Kaplan discloses a tubular member that has the same open tubular configuration that the present invention illustrates and that upon inserting the tubular member disclosed by Kaplan into the fallopian tube epithelialization will occur. The Examiner states that the tubular member disclosed by Kaplan and the fibrous material is capable of occluding the fallopian tube and enhancing tissue growth into the tubular member. The Examiner states that the tubular member disclosed by Kaplan is capable of being secured to the walls of a fallopian tube. The Examiner further states that Kaplan is designed to be inserted into a body lumen and that because Kaplan is made of a shape memory material the Kaplan device will expand and later contract to occlude a body lumen.

Applicants respectfully disagree with the Examiner, again traverse the rejection, and respectfully request reconsideration.

A. Kaplan Teaches Away From the Present Invention

Kaplan discloses stents that are "particularly useful for preventing restenosis of dilated body lumens, such as blood vessels." Abstract. (Emphasis added.) Kaplan also discloses that "what is needed in the art are devices and methods for the prevention of abrupt closure and/or restenosis following dilation of blood vessels." Col. 2, lines 6-8. (Emphasis added.) Kaplan also discloses that the "present invention provides devices and methods for treating body lumens

particularly for preventing restenosis of blood vessels following dilation of stenotic segments." Col. 4, lines 42-45 (Emphasis added). Kaplan discloses:

> While angioplasty has gained wide acceptance, it suffers from two major problems, i.e. abrupt closure and restenosis. Abrupt closure refers to the acute occlusion of a vessel immediately after or within the initial hours following a dilatation procedure. Abrupt closure occurs in approximately one in twenty cases and frequently results in myocardial infarction and death if blood flow is not restored in a timely manner. The primary mechanisms of abrupt closures are arterial dissection and/or thrombosis. It is postulated, that the ability to deliver agent (e.g. antithrombotic) directly into the arterial wall at the time of angioplasty could reduce the incidence thrombotic acute closure.
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> Restenosis refers to the re-narrowing of an artery after an initially successful angioplasty. Restenosis occurs within the initial six months after angioplasty and is due to the proliferation and migration of the cellular components of the arterial wall. It is postulate that the delivery of agent(s) directly into the arterial wall would interrupt the cellular events leading to restenosis.
>
> Medical prevention of abrupt closure and restenosis has not been entirely successful. Endovascular stents have been placed in the dilated segments to mechanically block abrupt closure and restenosis. Unfortunately, such stents have a high rate of thrombotic abrupt closure and have not significantly reduced restenosis.
>
> What is needed in the art are devices and methods for the prevention of abrupt closure and/or restenosis following dilation of blood vessels. In particular, it would be desirable to provide devices and methods which can provide antithrombic and other medications to regions of a blood vessel which have been treated by angioplasty or other interventional techniques, such as atherectomy, laser ablation, or the like . . . Surprisingly, the present invention fulfills these and other needs.

Col. 1, line 41 – col. 2, line 20

Thus, to prevent restenosis or the closure of blood vessels Kaplan discloses "A delivery matrix including at least one filament . . . interlaced with the tubular structure and expandable therewith from the initial diameter to the enlarged diameter." Col. 3, lines 3-6. The delivery matrix is suitable for the delivery of a variety of pharmaceutical and other therapeutic agents such as anti-thrombotic agents and other agents that will act to prevent thrombosis and restenosis due to endothelial proliferation. Col. 7, line 53 to col. 8, line 3.

Thus, the problem that Kaplan is trying to solve is the restenosis or closure of blood vessels that have been previously opened by the placement of a stent. In other words, Kaplan teaches how to prevent the occlusion of the blood vessel after it has been opened. To solve the problem a delivery matrix is provided that elutes drugs that assist in preventing the open blood vessel from closing. Kaplan does not teach, suggest or disclose using a stent to occlude a body lumen. In fact, the Kaplan device is the antithesis of occlusion and thus teaches away from occlusion. The Examiner states that Kaplan discloses in figures 1-6C a device for enlarging body lumens that anticipates a device for occluding a body lumen passageway. Applicants agree with the Examiner that Kaplan discloses a device for enlarging body lumens. However, the Examiner ignores that fact that Kaplan teaches maintaining the body lumens open. Further, Applicants disagree with the Examiner that a device that is designed to enlarge and open a body lumen, and maintain the body lumen open, anticipates or makes obvious a device for occluding or closing a body lumen. If anything, Kaplan's device distinctly and clearly teaches away from the present invention.

In *U.S. v. Adams*, the Supreme Court held that one important indicium of nonobviousness is "teaching away" from the claimed invention by the prior art. In short, "teaching away" is the antithesis of the art suggesting that the person of ordinary skill go in the claimed direction, i.e. occlusion. Teaching away from the art is a per se demonstration of the lack of prima facie obviousness. The Adams court stated that "despite the fact that each of the elements of the Adams battery was well known in the prior art, to combine them as did Adams required that a person reasonably skilled in the prior art must ignore" the teaching away of the prior art. *U.S. v. Adams*, 383 U.S. 39, 148 USPQ 479 (1966). More recently, the Federal Circuit held that "When the prior art teaches away from combining certain known elements, discovery of successful means of combining them is more likely to be nonobvious. *KSR International Co. v. Teleflex Inc.*550 U.S. at ___, 82 USPQ2d at 1385, 1395 (2007). See also MPEP §2143 A, Example 1. Again, teaching away from the art is a per se demonstration of the lack of prima facie obviousness. In re Fine, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988).

The Examiner states that Kaplan discloses that the tubular member is configured to promote epithelialization referring to col. 7, lines 52-66. Applicants find no such disclosure. First, "endothelial" cells line a blood vessel, not "epithelial" cells. Therefore, Kaplan could not

possibly teach or disclose that the tubular member is configured to promote epithelialization. Notwithstanding the difference between endothelial and epithelial cells, the Examiner's statement is clearly contrary to Kaplan's stated purpose for his invention. If the device of Kaplan promoted endothelialization, its intended function would be destroyed, i.e. to maintain the patency of the open blood vessel. Applicants respectfully request that the Examiner point to the column and line number where Kaplan discloses that its tubular member is configured to promote epithelialization or endothelialization. There is none. The entire teaching of Kaplan is directed to preventing the closure of vessels. For example:

> Methods for preventing stenosis or restenosis of bodily fluid lumens are also provided. Hereinafter, the phrase "bodily fluid lumens" refers to body cavities which contain or transmit body fluids. This includes, but is not limited to, both arterial and venous blood vessels, the common and cystic bile ducts, the ureters, the urethra, central nervous system ventricles, and the like. Segments of bodily fluid lumens which have been dilated or which are at risk for stenosis may be protected from occlusion by inserting a stent comprising a tubular member . . .

Col. 9, lines 48-58 (Emphasis added.)

Moreover, the Examiner seeks to combine Kaplan with the invention of Mariant stating that Mariant teaches an occlusion device comprising fibers 12 that permit tissue growth concluding that it would have been obvious to one having ordinary skill in the art to modify the filaments of Kaplan with the fiber bundles disclosed by Mariant. Applicants disagree. First, one skilled in the art would not modify the filaments of Kaplan with the fibers of Mariant quite simply because Kaplan teaches away from occlusion. Second, as discussed below, one skilled in the would not be motivated to modify the filaments of Kaplan with the fibers disclosed by Mariant because the intended function of the Kaplan device, i.e. to maintain the patency of the lumen of the vessel, would be destroyed.

B. References Are Not Properly Combinable if Their Intended Function is Destroyed.

If a prior art reference requires some modification in order to meet the claimed invention and such a modification renders the prior art invention being modified unsatisfactory for its intended purpose, one of ordinary skill in the art would not have found a reason to make the claimed modification. MPEP § 2143.01. The Examiner states that Kaplan in view of Mariant

makes Applicants' claimed invention obvious. As discussed above, Kaplan discloses a stent for preventing occlusion of a body lumen. The Examiner states that Mariant discloses in FIGS. 1-6 an occlusion device comprising fibers 12 that permit tissue growth referencing col. 5, lines 45-51. The Examiner then states that one having ordinary skill in the art at the time the invention was made that the fibers as taught by Mariant could be substituted for the fibers disclosed by Kaplan in order to permit tissue growth into the tubular member. Applicants disagree. If such a modification of the Kaplan device were made, it would promote tissue in-growth and would make the Kaplan device completely unsatisfactory and unusable for its intended purpose, i.e. preventing the restenosis or closure of blood vessels following dilation of stenotic segments. The intended purpose of the Kaplan device, i.e. to maintain the vessel open, would be destroyed. See, MPEP § 2143.01.

The Examiner further uses Phelps in combination with Kaplan and Mariant stating that the fibrous mesh as taught by Phelps could be used to increase tissue growth around and inside of the tubular open framework. Again, Applicants assert that if the fibers of Kaplan were modified with the fibers of Mariant and Phelps the intended function of the Kaplan device would be destroyed. Thus, one of ordinary skill in the art would not be motivated to combine Kaplan with Mariant and Phelps. If a prior art reference requires some modification in order to meet the claimed invention and such a modification renders the prior art invention being modified unsatisfactory for its intended purpose, one of ordinary skill in the art would not have found a reason to make the claimed modification. MPEP § 2143.01.

III. CONCLUSION

If the Examiner believes that a teleconference would be of value in expediting the allowance of the pending claims, the undersigned can be reached at the telephone number listed below. This response in being filed within the three-month statutory period for response, i.e. on or before March 27, 2008. Therefore it is believed that no fees are required. However, if the Commissioner determines that fees are required then Applicants authorize the Commissioner to charge any such fees or credit any overpayment to Deposit Account No. 50-1901 (Reference No. 687-470/US).

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Respectfully submitted,

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